K040752

APR - 7 2004

510 (k) Summary of Safety and Effectiveness for Elastomeric Infusion Pump *DOSI-FUSER*

1.	Submitter's name:	LEVENTON S.A.
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	Contact person:	Mr. Joaquim Soriano (General Manager)
	Date:	28.09.01
2.	Trade name:	DOSI-FUSER
	Common name:	Elastomeric pump
	Classification name:	Infusion pump (per 21 CFR 880.5725)
3.	Legally marketed device:	SINGLEDAY INFUSOR 2 ml./h
4.	Description:	DOSI-FUSER is an Elastomeric Infusion Pump. It is a sterile and disposable infusion device, that operates by the action of compression of the elastomeric balloon that contains the liquid to instill. The liquid is supplied at a constant flow rate.
5.	Intended use:	The DOSI-FUSER is designed to provide parenteral drug infusions at a constant flow without impeding patient mobility. It is indicated for patients requiring slow infusion of medication, which may be administered intravenously or via intra-arterial, epidural or subcutaneous routes. The device allows patients to be mobile, thus making it suitable for ambulatory use.

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2. DOSI-FUSER is a system for continuous and portable infusion of medication with a self-pressured container. It is a sterile and disposable device.

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   a. The fluid contained in the balloon passes to the tube connected to the reservoir, goes through the filter (where particles in the fluid are retained and air bubbles are removed) and reaches the capillary, which fixes the flow rate that the patient will receive. The connector at the extreme of the tube must obviously be connected to a cannula, needle, etc. that contacts the blood vessel.

   b. DOSI-FUSER is applicable to be used with a wide range of drugs, not for a specific drug.

   c. As stated before, DOSI-FUSER is not intended for a specific use.

   d. This product is not intended in any case for the delivery of blood and blood products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Leventon, S.A.
C/O Ms. Stefan Preiss
Responsible Third Party Official
TUV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K040752
Trade/Device Name: DOSI-FUSER
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 9, 2004
Received: March 24, 2004

Dear Ms. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

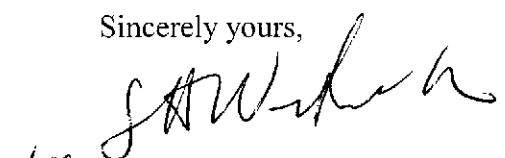
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-56. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040752

Device Name: DOSI-FUSER

Indications for Use:

The DOSI-FUSER is designed to provide parenteral drug infusions at a constant flow without impeding patient mobility. It is indicated for patients requiring slow infusion of medication, which may be administered intravenously or via intra-arterial, epidural or subcutaneous routes. The device allows patients to be mobile, thus making it suitable for ambulatory use.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K040752

(Posted November 13, 2003)

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